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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,427	04/04/2006	Hugh Semple Munro	101713-5026	3197

28977 7590 03/02/2010
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EXAMINER

JACKSON, BRANDON LEE

ART UNIT	PAPER NUMBER
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3772

MAIL DATE	DELIVERY MODE
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03/02/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,427	Applicant(s) MUNRO ET AL.	
	Examiner BRANDON JACKSON	Art Unit 3772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to amendments/arguments filed 11/13/2009. Currently, claims 1-20 are pending in the instant application.

Oath/Declaration

The Declaration of Patrick Trotter ("Affidavit") Pursuant to 27 C.F.R. 1.132 is noted for its clarification of the how to change absorbencies of the same materials at the molecular level. However, this distinction with respect to the prior art of record is moot because the Webster reference teaches a polyurethane with a continuous internal structure and polyurethane with a cellular structure, described further below.

Response to Arguments

Applicant's arguments filed 11/13/2008 have been fully considered but they are not persuasive. Applicant argues Webster does not disclose a hydrogel. Applicant describes hydrogel as "...not to be considered limited to gels which contain water, but extend generally to all hydrophilic gels and gel compositions, including those containing organic non-polymeric components in the absence of water." (App.'s Spec. page 1, lines 9-12) Webster discloses composition (2, 1) comprising hydrophilic polyurethane that contains 20 to 40% water (col. 3, lines 14-16). Therefore, the Webster composition (2, 1) meets Applicant's description of a hydrogel.

Applicant argues the layers of the of the Webster device are not made of the same material. However, Webster discloses the first layer is made of polyurethane (col.

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2, lines 49-64) and the second layer is made of polyurethane (col. 4, 47-52). The difference between the first and second layer is the amount of hydration in the layer, which varies how hydrophilic the polyurethane will be; this is not a difference in the type of material, just how it has been treated prior to usage.

Applicant argues that the terms polyamide and polyurethane describe structures within a molecule, but do not adequately describe the molecule. However, a material is still the same material, whether or not it has experiences a varied amount of heat, pressure or hydration, which would cause its physical traits to vary. Therefore, the Office maintains the two layers made of the polyurethane with two different amounts of hydration are still both made of the same material, which is polyurethane.

Applicant argues the Webster layers are not made of cellular structure and a continuous internal structure. However, the hydrophilic layer is preferably made of a synthetic polymer (col. 2, lines 43-44); however, if it is merely a preference then it may also be made of a natural polymer, which would have an internal cellular structure. The less hydrophilic layer is made of a synthetic polymer (col. 2, lines 47-48), therefore, it would have not have a cellular structure, but a continuous internal structure. Therefore, Webster teaches a hydrophilic layer with an internal cellular structure and a hydrophilic layer with a continuous internal structure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-5, 13-15, and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Webster (US Patent 4,541,426). Webster discloses a wound dressing comprising a first portion (2) comprising a flexible plasticized hydrophilic polymer matrix with an cellular internal structure (col. 2, lines 43-44) because a natural polymer would have a cellular structure, a second portion (1) comprising a flexible plasticized hydrophilic (col. 2, lines 4-6) matrix that is relatively continuous internal structure because it is a synthetic polymer (col. 2, lines 43-44), and apertures (4) providing fluid communication (fig. 1) between the first and second portions (2, 1). The hydrogel composition (2, 1) is adhered to the skin, wherein the second portion (1) has a wound facing surface that contacts the skin (col. 5, lines 10-12), as shown in Fig. 3. The wound dressing further comprises an absorbent layer (6) for receiving fluid through the hydrogel composition (2, 1) and comprising a layer of hydrophilic foam (col. 7, lines 54-56), a removable cover sheet (3) to cover the wound facing surface of the hydrogel composition (2, 1). The wound dressing is sterile and packaged in a microorganism-impermeable container (col. 5, lines 21-23). The hydrogel composition (2, 1) comprises a synthetic polymer; therefore, it inherently must have been formed through the polymerization of at least one monomer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster (US Patent 4,541,426). Webster substantially discloses the claimed invention; see rejection to claim 1 above. Webster further discloses the first portion to comprising a porous internal structure and the second portion that is relatively continuous, not as porous. Therefore, the ratio of cell void between the first portion and the second portion that is greater than 1:1. The 1:3 ratio provides no advantage, is not used for a particular purpose, and does not solve a stated problem. The Webster device would function equally as well with a 1:3 ratio or greater. Therefore, it is a mere design choice and would be obvious to one of ordinary skill in the art at the time of the invention to modify the ratio of sell voids to be greater than 1:3.

With respect to claim 20, Applicant fails to disclose criticality to why the two portions should be integrally formed rather than laminated together. In addition, Applicant's specification states the two portions may be integrally formed or may be laminated together (pg. 10, lines 3-5). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to form the two portions by laminating or integrating. The method step would have resulted from the use of the Webster device.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Webster (US Patent 4,541,426) in view of Takahashi et al. (US Patent 5,972,452). Webster substantially discloses the claimed invention; see rejection to claim 1 above. Webster fails to disclose the apertures of the second portion continuing into the first portion without penetrating it entirely. However, Takahashi teaches a wound dressing (10) comprising apertures (24) that penetrate a layer (20) without fully penetrating the layer (20). Therefore it would be obvious to one of ordinary skill in the art at the time of the invention to modify the apertures in the first portion to be varying lengths that do not fully penetrate the layer, as taught by Takahashi, in order to vary the flexibility of the layer as desired by the user.

Claims 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster (US Patent 4,541,426) in view of Nielsen (US Patent Application Publication 2003/0153860). Webster substantially discloses the claimed invention; see rejection to

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claim 1 above, and a wound dressing having a substantially uniform thickness (fig. 3).

Webster fails to disclose an absorption capacity between 30 and 10,000 %, a water uptake rate of at least 2 micro-L/s, a thickness between about 0.5 to 10 mm, a substantially liquid-impermeable backing layer, and adhesive on the backing layer.

However, Nielsen teaches a wound dressing (fig. 1) comprising a substantially liquid-impervious (par. 0054) backing layer (1) covering an absorbent layer (2) and whose edges extend beyond the absorbent layer (2), an adhesive layer (3) disposed on the backing layer (1) all the way to the edges of the backing layer (1) and on a portion of the absorbent layer (2) while extending beyond the absorbent layer (2), rapid fluid uptake (par. 0072), and high absorption capacity (par. 0029). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Webster device to have a backing layer and adhesive that extend beyond the absorbent pad, as taught by Webster, in order to trap liquid within the absorbent layer and adhesive only on a portion of the hydrogel composition in order to facilitate rapid fluid uptake. The absorption capacity between 30 and 10,000%, fluid uptake rate of at least 2 micro-L/2, and thickness between about 0.5 to 10mm provides no advantage, is not used for a particular purpose, and does not solve a stated problem. The Webster/Nielsen device would function equally as well with an absorption capacity between 30 and 10,000%, a fluid uptake rate of at least 2 micro-L/2, and a thickness between about 0.5 to 10mm. Therefore, it is a mere design choice and would be obvious to one of ordinary skill in the art at the time of the invention to modify the Webster/Nielsen device to have an

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absorption capacity between 30 and 10,000%, a fluid uptake rate of at least 2 micro-L/2, and a thickness between about 0.5 to 10mm.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webster (US Patent 4,541,426) in view of Gilman et al. (US Patent 5,811,116). Webster substantially discloses the claimed invention; see rejection to claim 1 above. Webster fails to disclose a removable cover provided with projections into the apertures of the hydrogel sheet. However, Gilman discloses a patch (14) comprising a removable cover (22) with projections that extend into the aperture (col. 4, lines 25-27). Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the Webster device with the removable cover, as taught by Gilman, in order to preserve the shape of the apertures before removal of the release cover.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRANDON JACKSON whose telephone number is (571)272-3414. The examiner can normally be reached on Monday - Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571)272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brandon Jackson/
Examiner, Art Unit 3772

/BLJ/

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772